32. the method according to Claim 28 for rapid, accurate diagnosis *S. pneumoniae* -caused meningitis.

REMARKS

Filed herewith is a new drawing which is believed to obviate the criticisms made in the "Notice of Drafts person's Patent Drawing Review", which is appended to the action but is not mentioned in the action itself.

By the accompanying amendment, Applicants have made a series of amendments to correct typographical errors, (including misspellings,) and to supply obviously missing words. None of these amendments changes the teachings of the application or introduces new matter.

Also, by this amendment, it has been made clear that this application describes an integral process which commences with the extraction and purification by a defined method of the C-polysaccharide cell wall antigen common to all of the 83 or 84 scrotypes of *S. pneumoniae,* which antigen is then coupled to a chromatographic column and used to purify polyclonal antibodies to *S. pneumoniae*, which antibodies are in turn used to detect the unpurified C-polysaccharide cell wall of *S. pneumoniae* present in mammalian body fluids via assay procedures. To assist in making this clear, Claim 10 now recites that the cell wall C-polysaccharide antigen of step (a) is obtained by the method of Claim 1. To further assist, Claim 20 now recites an immunochromatographic process according to Claim 17, which as a dependent claim, incorporates all the recitations of Claim 10. Further, Claim 30 recites that the device it covers is " for use in the process of Claim 20".

Applicants hereby traverse the restriction requirement. The Examiner's effort to show

distinctness among the various groupings set forth in the office action is highly speculative, and rests on unjustified and insupportable assumptions. For example, it is extremely speculative to assume that the Havas *et al* method of purification will give an antigenic product having the same properties as that obtained by applicants method of extracting and purifying the antigen. To make such large assumptions about highly complex molecules in the absence of evidence is tantamount to creating an imaginary, wholly unverifiable, hypothesis rather than drawing a fair and reasoned conclusion based upon what the art fairly teaches or suggests. Moreover, these assumptions are inconsistent with the existing body of prior art, which recognizes that methods of extracting and purifying antigens have a considerable effect upon the solubility characteristics, the reactivity, the retention or the loss-by-removal of particular functional groups, etc. of the extracted, purified product.

Furthermore, Claim 2 clearly covers only a C-polysaccharide cell wall antigen of *S. pneumoniae* obtained by the process of Claim 1 while Claims 10-30 as now amended make very clear that the claimed assay requires using an antigen obtained by the method of Claim 1 to purify polyclonal antibodies to *S. pneumoniae* which in turn impart very high specificity and sensitivity to assays for detecting the presence of the crude form of the original antigen in fluids obtained from *S. pnuemoniae*-infected mammals.

It is clear that the restriction requirement herein has been indiscriminately made without considering whether the seven "inventions" allegedly perceived could each support a different patent. The Examiner is referred to M.P.E.P. 803 which is careful to state that:

"Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are

either independent... or distinct..." (Emphasis added)

In other words, if separate patents could not or should not be issued on the parts of an integral process, it is of no moment whether these parts are "distinct".

Here, the process of extracting and purifying the antigen is critical to its ability to purify raw polyclonal antibodies to *S. pneumoniae* and this latter purification process is critical to the ability of the antibodies, which are subjected to it detect, with exceptional specificity and sensitivity, the original unpurified antigen in fluids obtained from *S. pneumoniae* infected patients. The attempt to break the integral process into segments would deprive that process of some of its essential parts. Similarly, the suggestion that the preferred immunochromatographic assay, (preferred for its speed as well as its specificity and sensitivity) could somehow support a different patent from a patent more broadly covering assays for *S. pneumoniae* generally that are improved by substituting polyclonal antibodies purified according to this invention for unpurified raw polyclonal antibodies, seems to be grounded in an impulse toward inefficient and indiscriminate proliferation of similar and overlapping patents. Likewise, that attempted restriction between the immunochromatographic ("ICT") assay process and the specific device embodiment needed to practice that process cannot properly be countenanced under the statute. In particular, applicants urge that Claims 10-32 inclusive, all drawn to assay methodology except for Claim 30 (which actually covers the same invention, but in the form of a product, as the ICT method covered by Claims 20 and its dependent claims.), definitely belong in and are able to support only one patent. The Office Action's grouping of these claims in two different groups apparently rests on Applicant's initial failure to specify in a claim (as distinguished from within the description of the invention that

underpins the claims) that step (a) of Claim 10 and all of its directly and indirectly dependent claims 11-29, 31 and 32 require that the C-polysaccharide cell wall antigen of *S. pneumoniae* be extracted and purified by the process of Claim 1 (See Office Action page 5). The Examinier's attempted distinction between different assay methods (Office Action page 6) ignores the important point that patentability in every instance is grounded upon using the antibodies to *S. pneumoniae* that have been purified by affinity purification with the *S. pneumoniae* C-polysaccharide cell wall antigen that was itself extracted and purified by the method of Claim 1. In other words, the patentability of all the assay methods rests on the use, to detect *S. pneumoniae* in mammalian fluids, of antibodies purified as described in this application, using the antigen identified in this application that was itself extracted and purified according to the method of Claim 1 as described in this application.

Reconsideration of the restriction requirement is respectfully requested in the premises.

For the nonce, Applicants provisionally elect the method of claim 10 and its directly and indirectly dependent claims for further prosecution.

Respectfully submitted,

Mary Helen Sears, Registration No. 19,961
Attorney for Applicants
The M.H. Sears Law Firm Chartered
910 Seventeenth Street, N.W., Suite 800
Washington, D.C. 20006